UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	No.
	)	
v.	)	
	)	COMPLAINT FOR
INVACARE CORP., a corporation,	)	PERMANENT INJUNCTION
GERALD B. BLOUCH,	)	
and RONALD J. CLINES,	)	
individuals,	)	
	)	
	)	
Defendants.	)	
_____	)	

INTRODUCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Invacare Corp. ("Invacare"), a corporation, and Gerald B. Blouch and Ronald J. Clines, individuals (hereafter, collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for

introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820;

B. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of the Act, 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish material or information respecting certain devices to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Part 803;

C. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. §§ 351(h), as described in paragraph A above, and misbranded within the meaning of 21 U.S.C. §§ 352(t)(2), as described in paragraph B above, while such devices are held for sale after shipment in interstate commerce;

D. 21 U.S.C. § 331(q)(1)(B), in that Defendants fail to furnish notification or other material or information to FDA as

required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Part 803.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Invacare is incorporated under the laws of Ohio. Invacare manufactures and distributes articles of device, within the meaning of 21 U.S.C. § 321(h), namely powered wheelchairs, at its facility located at 1200 Taylor Street, Elyria, Ohio ("Taylor Street facility"). All of Invacare's device design specifications for the powered wheelchairs and for powered beds are developed at its corporate headquarters, located at 1 Invacare Way, Elyria, Ohio ("Corporate facility"). Invacare's corporate headquarters also handles complaints and other aspects of the company's Quality Assurance program.

5. Gerald B. Blouch is the President and CEO of Invacare. He is the most responsible person at the firm, and oversees the firm's product development, product management, and international relations and sales. He performs his duties at 1 Invacare Way, Elyria, Ohio 44036.

6. Ronald J. Clines is Invacare's Director, Product Risk and Quality Engineering. Up until 2011, Mr. Clines was the Director of Regulatory Affairs and Quality Systems. Mr. Clines is responsible for FDA regulatory compliance, including complaint handling, risk assessments, and design control. He performs his duties at 1200 Taylor Street, Elyria, Ohio.

7. Defendants have been, and are now, manufacturing and distributing in interstate commerce various articles of devices, as defined by 21 U.S.C. § 321(h), including, but not limited to, several models of manual and powered wheelchairs and the components thereof.

8. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that they are intended to affect the structure or any function of the body of man.

LEGAL STANDARDS

9. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

10. The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a

violation of the Act, 21 U.S.C. § 331(a).

11. Under the Act, every manufacturer of a device intended for human use must submit certain reports and other information to FDA "as the Secretary may by regulation reasonably require to assure that the device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." 21 U.S.C. § 360i.

12. Every manufacturer is required to submit a medical device report ("MDR") to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that its marketed device may have caused or contributed to a death or serious injury, and to conduct an adequate investigation into MDR reportable events. 21 C.F.R. §§ 803.50(a), 803.50(b)(3).

13. A device is misbranded, pursuant to 21 U.S.C. § 352(t)(2), if a device manufacturer fails or refuses to submit to FDA MDRs as required by 21 CFR Part 803.

14. The introduction or delivery for introduction into interstate commerce of a misbranded article of device is a violation of the Act, 21 U.S.C. § 331(a).

15. The adulteration or misbranding of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the Act, 21 U.S.C. § 331(k).

16. The failure or refusal to furnish any notification or other material or information required under 21 U.S.C. § 360i, and its

implementing regulations at 21 C.F.R. Part 803, is a violation of the Act, 21 U.S.C. § 331(q)(1).

AUGUST 2011 INSPECTIONS

17. FDA inspected Invacare's Corporate facility on July 18-August 11, 2011 ("August inspection"). The Corporate facility does not physically produce devices, but handles all device design procedures, and much of the complaint handling and the corrective and preventive action ("CAPA") procedures for the entire firm. During the August 2011 inspection, the FDA investigators documented numerous violations of the QS regulation at the Corporate facility. Many of these violations related directly to the manufacture powered wheelchairs at Invacare's Taylor Street facility. FDA investigators observed the following violations of the QS regulation set forth in 21 C.F.R. Part 820:

A. Defendants fail to establish and maintain adequate procedures for implementing corrective and preventive action that shall include requirements for using appropriate statistical methodology where necessary to detect recurring quality problems, in violation of 21 C.F.R. § 820.100(a)(1);

B. Defendants fail to establish and maintain adequate design validation procedures to ensure that devices conform to defined user needs and intended uses, to complete proper risk analysis, and to document the results of the validation, in violation

of 21 C.F.R. § 820.30(g);

C. Defendants fail to establish and maintain adequate procedures for identifying, documenting, validating, or where appropriate, verifying, reviewing, and approving design changes before their implementation, in violation of 21 C.F.R. § 820.30(i);

D. Defendants fail to establish and maintain adequate procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, in violation of 21 C.F.R. § 820.30(d);

E. Defendants fail to establish, maintain, and document adequate procedures to ensure that the design inputs are appropriate and address the intended use(s) of the device, including the needs of the user and the patient, in violation of 21 C.F.R. § 820.30(c);

F. Defendants fail to establish and maintain procedures for receiving, reviewing, and evaluating complaints, in violation of 21 C.F.R. § 820.198(a);

G. Defendants fail to document corrective and preventive actions, in violation of 21 C.F.R. § 820.100(b);

H. Defendants fail to adequately maintain complaint files by a designated unit to include a record of the complaint investigation, in violation of 21 C.F.R. § 820.198(e);

I. Defendants fail to ensure that all personnel are trained to adequately perform their assigned responsibilities, in

violation of 21 C.F.R. § 820.25(b); and

J. Defendants fail to have sufficient personnel with experience to assure that all activities required by 21 C.F.R. Part 820 are correctly performed, in violation of 21 C.F.R. § 820.25(a).

18. During the August 2011 inspection of the Corporate facility, FDA investigators also determined that Defendants fail to comply with the regulations regarding the submission of MDRs set forth at 21 C.F.R. Part 803. FDA investigators observed:

A. Defendants failed to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that their marketed devices may have caused or contributed to a serious injury, as required by 21 C.F.R. § 803.50(a)(1);

B. Defendants failed to report to FDA no later than 30 calendar days after they became aware that a device that they distributed had malfunctioned and was likely to cause or contribute to a death or serious injury, in violation of 21 C.F.R. § 803.50(a)(2); and

C. Defendants do not have an adequate MDR procedure that describes an internal system that provides for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 C.F.R. § 803.17. Defendants' MDR reporting procedures fail to describe how

the firm will submit supplemental or follow-up reports, as required by 21 C.F.R. § 80.56, define how the firm will conduct an investigation and evaluation of each event, or establish documentation and record-keeping requirements.

19. FDA investigators also inspected Invacare's Taylor Street facility from July 18 - August 8, 2011 (August Taylor Street inspection). Defendants manufacture powered wheelchairs and their accessories at the Taylor Street facility. During that inspection, the FDA investigators documented numerous violations of the QS regulation at the Taylor Street facility, including, but not limited to, the following:

A. Defendants fail to validate certain manufacturing processes, in violation of 21 C.F.R. § 820.75(a);

B. Defendants fail to review, validate, and document changes or process deviations and perform revalidation where appropriate, in violation of 21 C.F.R. § 820.75(c);

C. Defendants fail to establish and maintain adequate procedures for implementing corrective and preventive actions, as required by 21 C.F.R. § 820.100(a);

D. Defendants fail to establish and maintain adequate procedures to control product that does not conform to specified requirements, in violation of 21 C.F.R. § 820.90(a);

E. Defendants fail to establish, maintain and document

adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure the product meets its current approved specifications, and to document the rework and reevaluation activities, including a determination of any adverse effect from the rework on the product, in violation of 21 C.F.R. § 820.90(b)(2);

F. Defendants fail to adequately establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met, in violation of 21 C.F.R. § 820.70(g)(1); and

G. Defendants fail to establish and maintain adequate procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, in violation of 21 C.F.R. § 820.25(b).

20. At the conclusion of both August 2011 inspections, FDA investigators issued to Defendants a List of Inspectional Observations ("Form FDA 483"), detailing their violations of the Act and discussed the documented observations with the recipients, including Defendant Clines.

PRIOR INSPECTIONS

21. FDA inspected Invacare's Corporate facility previously in December 2010, December 2008, April 2005, October 2004, and September 2002. FDA inspected Invacare's Taylor Street facility previously

in December 2010, December 2008, and March 2003. At these inspections, FDA repeatedly observed and documented violations of the QS regulations similar to those cited above during the August 2011 inspections, including, but not limited to, violations involving: design controls (21 C.F.R. § 820.30); complaint handing (21 C.F.R. § 820.198); corrective and preventive action (21 C.F.R. § 820.100); nonconforming products (21 C.F.R. § 820.90); and production and process controls (21 C.F.R. § 820.70).

22. In addition to these QS violations, FDA investigators documented numerous violations of the MDR regulations at the majority of the previous inspections.

23. At the conclusion of each of the prior inspections, the FDA investigators issued a Form FDA 483 detailing Defendants' numerous violations of the Act to Defendants, and discussed the documented observations with them. Defendants promised corrections at the conclusion of each inspection.

PRIOR NOTICE OF VIOLATIONS

24. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

25. FDA issued an Untitled Letter, dated November 29, 2009, to Defendants, following the December 2008 inspections of the

Corporate and Taylor Street facilities. The letter addressed the MDR reporting violations observed at both facilities, and warned Defendants that further enforcement actions could occur if they did not correct the violations.

26. Invacare's Taylor Street facility also received a Warning Letter, dated August 3, 2003, following the March 2003 inspection. The Warning Letter discussed the QS violations involving design controls, complaint handling, and acceptance activities. In addition, the Warning Letter notified Defendants that failure to correct these deviations could result in further action, including injunction.

27. Representatives of Invacare also attended a regulatory meeting with FDA's Center for Devices and Radiological Health and Cincinnati District Office on October 24, 2011. At this meeting, Defendants stated that they were aware of the violations at their facilities, and were taking steps to correct them.

28. At the conclusion of each of FDA's inspections of the firm, the FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act to a responsible individual at the firm, and discussed the documented observations with the recipient.

29. Defendants made promises to correct their violations in written responses to the August 2011 inspections, dated August 29, September 15, September 29, and October 28, 2011. None of these

responses contained adequate evidence that Defendants have corrected their deviations.

30. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), and (q).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. § 351(h), or misbranded within the meaning of 21 U.S.C. § 352(t)(2);

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(h), and misbranded within the meaning of 21 U.S.C. § 352(t)(2), while such article is held for sale after shipment in interstate commerce; and

C. violating 21 U.S.C. § 331(q)(1)(B), by failing to

furnish notification or other material or information required by 21 U.S.C. § 360i.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) any device, at or from its Corporate and Taylor Street facilities, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA; and

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' Corporate and Taylor Street facilities to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

STEVEN M. DETTELBACH
United States Attorney

s/ Adam Hollingsworth____
ADAM HOLLINGSWORTH (MA660727)
Assistant United States Attorney
804 West Superior Ave.
Suite 400
Cleveland, OH 44113
(216) 622-3781 PHONE
(216) 522-2404 FAX
adam.hollingsworth@usdoj.gov

OF COUNSEL:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH DICKINSON
Acting Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

TARA BOLAND
Associate Chief Counsel
United States Department of Health and Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-8549

STUART F. DELERY
Principal Deputy Assistant Attorney General
MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director, Consumer Protection Branch

s/ Ann Entwistle_____
ANN F. ENTWISTLE
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
(202) 305-3630 PHONE
(202) 514-8742
Ann.F.Entwistle@usdoj.gov